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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,752	12/11/2000	Janet A. Warrington	3308.3	4824

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/28/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,752

Applicant(s)

WARRINGTON ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 11, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to Paper No. 13, filed on July 11, 2002. Currently, claims 2 and 4-9 are pending. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the 112 2nd paragraph rejections have been withdrawn in light of Applicants amendments.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY

APPLICANTS AMENDMENTS TO THE CLAIMS

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 2 over “reference samples of known disease state that is matched to said experimental sample in reproductive state” because it is not clear as to what is being “matched” because it is uncertain as to what encompasses “reproductive state”. The specification does not define or teach one of skill in the art as to what is meant by “reproductive state”.

The specification states:

The parameters that are considered in determining physiological state include, but are not limited to age, gender, ethnic origin and reproductive state, which includes, but is not limited to menstrual state, post-partum, pregnancy, lactation and nulliparity”

Given this description, it is not clear as to what is meant by “reproductive state”.

Applicants have only listed possible parameters (and explicitly a non-exhaustive list of parameters) that might be considered to fall under the umbrella of “reproductive state”. This partial list does apprise one of ordinary skill in the art of the scope of “reproductive state”, and the metes and bounds of this recitation are unclear. For example, can “reproductive state” refer only to gender, or whether or not a female is capable of reproduction, etc.

B) Claims 4-9 over “reproductive status” and “reproductive state” because it is unclear as to what are meant by these recitations. These recitations are not defined in the specification, nor do the claims or specification apprise one of ordinary skill in the art of their scope (see discussion of “reproductive state” above). For example, do these recitations refer to gender, or whether or not a female is capable of reproduction, etc. Claim 4 is also indefinite over “matching indicators of reproductive status” because the specification is silent as to what is meant by or what the scope of “matching indicators of reproductive status” encompasses.

C) Claims 6-9 over “the method of claim 5 wherein said sample are matched according to...”, however claim 5 does not include a “matching” step, so it is not clear as to “matching” step claims 6-9 are referring to. Furthermore, claim 5 only refers to one sample, and therefore, it is unclear as to “samples” are being referred to in claims 6-9.

D) Claims 5-9 because the claims do not recite a final process step, which clearly relates back to the preamble. Claim 5 is drawn to “a method to identify the reproductive status”, but is final step is drawn to “identifying the physiological status”. Similarly, Claim 6 is drawn to “a method to identify marker of different reproductive states in women”, but the final step is drawn to “identify markers of different physiological states in humans”.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 2 and 4-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Friend et al. (USPN 6,218,122).

Friend teaches methods of diagnosing disease or physiological disorders by comparing expression profiles of an experimental sample with reference expression profiles (see abstract and cols. 2-14).

Specifically, Friend teaches:

[M]ethods for determining or monitoring the level of one or more disease states (i.e., the progression of one or more disease states) upon a subject by: (i) obtaining a diagnostic profile by measuring abundances of cellular constituents in a cell from a subject known or suspected of having a disease state (i.e., experimental sample); (ii) obtaining interpolated perturbation response profiles for each disease state being monitored by, first, obtaining response profiles by measuring abundances of cellular constituents (i.e., expression profiles) that occur in cells of an analogous subject or subjects (i.e., reference samples) at a plurality of levels of each disease state and second, interpolating the thus obtained response profiles; and (iii) determining the interpolated perturbation response profile for each disease state for which similarity is greatest between the diagnostic profile and a combination of the determined interpolated response profiles, according to some objective measure. The level of a particular disease state is thereby indicated by the disease level correlated to the thus determined interpolated response profile for that disease state.

(col. 3, ln. 3-26)

The reference teaches this method can be used for determining diseases/disorders such as uterine cancer, ovarian cancer and testicular tumors, which all may affect the reproductive status or state of an individual (see cols. 7-8, for example). Friend also teaches methods for monitoring the beneficial use or adverse effects of a therapy, such as drug treatment (i.e., pharmacological state) (col. 3, ln. 27-49, for example) in human patients (col. 4, ln. 58-59, for example). Friend also teaches that the analogous subject may or may not be of the same sex and/or approximate age (e.g., physiological status) (col. 14, ln. 9-12).

Applicants have amended the claims to include the recitations of “reproductive status” and “reproductive state”, however, these recitations are vague and do not differentiate the claimed invention from the teachings of Friend et al.

Conclusion

6. No claims are allowable.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1637


however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Alexander H. Spiegler
April 25, 2003


GARY BENZION, PH.D.
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